

# Respiratory Experience

*More than 30 staff with experience in respiratory projects, including*

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## A Wealth of Experience

At RTI Health Solutions, we have collaborated with our clients on more than 190 projects researching respiratory illnesses and diseases, respiratory treatment studies, and complications of respiratory illness and diseases. Our experience includes:

- Acute lung injury
- Acute respiratory infection
- Allergic rhinitis
- Asthma
  - Pediatric
  - Adult
- Chronic bronchitis
- COPD
- Cystic fibrosis
- Dyspnea
- Sinusitis

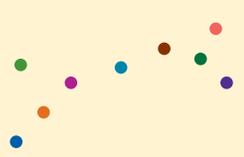
## Types of Projects

We have implemented a wide variety of studies to help our clients demonstrate treatment benefits and gain market access for respiratory products.

Recent projects have included:

- Epidemiology of disease
- Risk management plans
- Patient reported outcomes (PRO), instrument development, and psychometric validation
- PRO evidence dossiers to support labeling claims
- Survey development and implementation
- Outcomes research strategy development
- Observational studies
- Decision-analytic modeling to examine
  - Cost-effectiveness
  - Budget impact
- Meta-analyses
- Economic burden of illness studies
- Reimbursement dossiers (i.e., AMCP dossier)
- Database analyses using North American and European cross-sectional and longitudinal databases
- Benefit-risk preference studies
- Systematic literature reviews
- Global value dossiers
- Treatment pattern studies
- Drug utilization studies
- Consulting on drug development and clinical trial design
- Abstract and manuscript development

*(continued)*



## See How We've Helped Others

### Asthma Symptom and Rescue Medication Use Diary

We evaluated the measurement properties of an asthma symptom and rescue medication use (ASRMU) diary for clinical trials involving asthma patients aged 12 years or older. Our findings showed that the ASRMU diary captures the disease-specific concepts of greatest importance to asthma patients and provides important information for asthma diagnosis and treatment evaluation. The study results were published in *Journal of Asthma*, 2015 Feb;52(1):88-97.

### Literature Review to Evaluate COPD

We conducted a 10-year review of the epidemiologic literature to determine the incidence, prevalence, and mortality of chronic obstructive pulmonary disease (COPD) among men and women in 10 countries, across Europe and the US. The study showed that prevalence and incidence of COPD was greatest in men, while mortality rates have decreased in men and increased in women. This may be explained by differences in smoking patterns and a greater vulnerability in women to the adverse effect of smoking. Study results were published in the *International Journal of Chronic Obstructive Pulmonary Disease*, 2012;7:457-94.

### Database Study to Evaluate Live Influenza Vaccine in Children

We implemented a 3-year post-marketing study to monitor the use of live attenuated influenza vaccine (LAIV) among young children with asthma, recurrent wheezing, and compromised immune function—children cautioned to not receive LAIV. Identified vaccinated children were monitored for frequency of hospitalization or emergency department visits within 42 days after vaccination. Annual analyses showed the frequency of vaccination with LAIV among these cohorts was low. Evaluation of the frequency of hospitalization and ED visits among LAIV-vaccinated versus TIV-vaccinated children identified no new safety signals and confirmed a risk seen in clinical trials. Study results were published in *Vaccine*, 2012;30(42):6099-102.

### Cohort Study Assesses Antioxidants for Prevention of Respiratory Infection

We conducted a cohort study of 1509 Swedish men and women ages 20 to 60 to assess the protective effects vitamins C and E may have on lowering risk of acquiring upper respiratory tract infections (URTI). Among 1181 occurrences of URIs reported, the study showed no protective effect of vitamin E from food among either men or women. Conversely, the study showed a protective effect with vitamin C and E supplements among men who overall had a lower intake of vitamin C from food than women. Women's increased intake of vitamin C from food was sufficient to lower the risk of acquiring URTI. Study results were published in the *Journal of the American College of Nutrition*, 2011;30(4):248-58.

## Selected Publications By Our Staff

Long A, Rahmaoui A, **Rothman KJ**, Guinan E, Eisner M, Bradley MS, Iribarren C, Chen H, Carrigan G, Rosén K, Szeffler S. Incidence of malignancy in patients with moderate-to-severe asthma treated with or without omalizumab. *J Allergy Clin Immunol*. 2014 Sep;134(3):560-7.e.

Gimeno-Santos E, Frei A, Steurer-Stey C, de Batle J, Rabinovich RA, Raste Y, Hopkinson NS, Polkey MI, van Remoortel H, Troosters T, **Kulich KR**, Karlsson N, Puhan MA, Garcia-Aymerich J. Determinants and outcomes of physical activity in patients with COPD: a systematic review. *Thorax*. 2014 Aug;69(8):731-9.

Mahler DA, Decramer M, D'Urzo A, Worth H, White T, Alagappan VP, Chen H, Gallagher N, **Kulich K**, Banerji D. Dual bronchodilation with QVA149 reduces patient-reported dyspnoea in COPD: the BLAZE study. *Eur Respir J*. 2014 Jun;43(6):1599-609.

**Barrett AM, Clark MJ, DeMuro C**, Esser D. Proxy-reported questionnaires for young children with asthma: a structured review. *Eur Respir J*. 2013 Aug 1;42(2):513-26.

McKenna SP, Twiss J, **Crawford SR**, Oprandi NC, Tammaru M, Miravitlles M. The living with chronic obstructive pulmonary disease scale was successfully adapted for use in Southern European (Italian and Spanish) and Eastern European (Russian) cultures. *J Clin Epidemiol*. 2012 Aug;65(8):906-14.

Sansgiry SS, Joish VN, Boklage S, **Goyal RK**, Chopra P, Sethi S. Economic burden of pseudomonas aeruginosa infection in patients with cystic fibrosis. *J Med Econ*. 2012 Jan;15(2):219-24.

**Rycroft CE, Heyes A, Lanza L**, Becker K. Epidemiology of chronic obstructive pulmonary disease: a literature review. *Int J Chron Obstruct Pulmon Dis*. 2012;7:457-94.

Tennis P, Toback SL, **Andrews EB, McQuay LJ**, Bioinf M, Ambrose CS. A US postmarketing evaluation of the frequency and safety of live attenuated influenza vaccine use in nonrecommended children younger than 5 years: 2009-2010 season. *Vaccine*. 2012;30(42):6099-102.